

Substitute for form 1449A/PTO

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

(use as many sheets as necessary)

Application Number	09/171,909
Filing Date	05/09/2001
First Named Inventor	Roy-Chowdhury
Art Unit	1644
Examiner Name	Ronald B. Schwadron

Sheet	1	of	5	Attorney Docket Number	59046.000033
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U.S. PATENT DOCUMENTS

Examiner Initials	Cite No.	DOCUMENT NUMBER Number - Kind Code (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
P3j	1.	US- 5,849,285	12-15-1998	Selawry	
	2.	US- 5,872,154	02-16-1999	Wilson et al.	
	3.	US- 5,861,290	01-19-1999	Goldsmith et al.	
	4.	US- 5,935,575	08-10-1999	Lenardo et al.	
	5.	US- 6,358,509	03-19-2002	Ramanathan et al.	
	6.	US- 5,424,066	06-13-1995	Allen	

OTHER DOCUMENTS - NON-PATENT LITERATURE DOCUMENTS

Examiner Initials	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	TRANSLATION	
			YES	NO
P3j	7.	McMenamin et al., "Regulation of IgE Responses to Inhaled Antigen in Mice by Antigen-Specific $\gamma\delta$ T Cells," <u>Science</u> , 265:1869-1871 (1994)	<input type="checkbox"/>	<input type="checkbox"/>
P2j	8.	Pearson et al., "Effect of anti-CD4 Monoclonal Antibody Dosage When Combined With Donor Antigen for the Induction of Transplantation Tolerance," <u>Transplantation Proceedings</u> , 23(1):565-566 (1991)	<input type="checkbox"/>	<input type="checkbox"/>
	9.	Ali et al., "The use of DNA viruses as vectors for gene therapy," <u>Gene Therapy</u>, 1:367-384 (1994)	<input type="checkbox"/>	<input type="checkbox"/>
	10.	Benjamini, E. and Leskowitz, S. (Eds.), "Transplantation Immunology," <u>Immunology: A Short Course</u>, Ch.19, 347-367 (Wiley-Liss, Inc. 2nd ed. 1991)	<input type="checkbox"/>	<input type="checkbox"/>
	11.	Cantor, H.M. and Dumont, A.E., "Hepatic Suppression of Sensitization to Antigen Absorbed into the Portal System," <u>Nature</u>, 215:744-745 (1967)	<input type="checkbox"/>	<input type="checkbox"/>
	12.	Clare-Saltier et al., "Prevention of Diabetes in Nonobese Diabetic Mice by Dendritic Cell Transfer," <u>J. Clin. Invest.</u>, 90:741-748 (1992)	<input type="checkbox"/>	<input type="checkbox"/>
	13.	Dal et al., "Cellular and humoral immune responses to adenoviral vectors containing factor IX gene: Tolerization of factor IX and vector antigens allows for long-term expression," <u>Proc. Natl. Acad. Sci. USA</u>, 92:1401-1405 (1995)	<input type="checkbox"/>	<input type="checkbox"/>
	14.	Engelhardt et al., "Ablation of E2A in recombinant adenoviruses improves transgene persistence and decreases inflammatory response in mouse liver," <u>Proc. Natl. Acad. Sci. USA</u>, 91:6196-6200 (1994)	<input type="checkbox"/>	<input type="checkbox"/>



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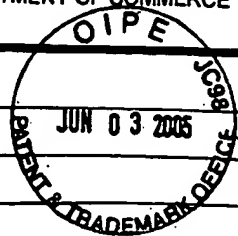


Substitute for form 1449A/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)

Application Number 09/356,294
 Filing Date 7/16/1999
 First Named Inventor Rabbani, et al.
 Art Unit 1644
 Examiner Name Ronald B. Schwadron



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OTHER DOCUMENTS - NON-PATENT LITERATURE DOCUMENTS

Examiner Initials	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	TRANSLATION	
	15.	Eron et al., "Randomised trial of MN gp120 HIV-1 vaccine in symptomless HIV-1 infection," <u>The Lancet</u>, 346:1547-1551 (1996)	<input type="checkbox"/>	<input type="checkbox"/>
	16.	Fang et al., "Gene Therapy for Hemophilia B: Host Immunosuppression Prolongs the Therapeutic Effect of Adenovirus-Mediated Factor IX Expression," <u>Human Gene Therapy</u>, 6:1039-1044 (1995)	<input type="checkbox"/>	<input type="checkbox"/>
	17.	Fauci, A., "Host factors and the pathogenesis of HIV-induced disease," <u>Nature</u>, 384:529-534 (1996)	<input type="checkbox"/>	<input type="checkbox"/>
	18.	Frank et al., <u>Samter's Immunologic Disease</u>, Vol. II (Little, Brown and Company 5th ed. 1995)	<input type="checkbox"/>	<input type="checkbox"/>
	19.	Fukushima et al., "Effects of Cyclosporin A on the Induction of Oral Tolerance," <u>Oral Tolerance: Mechanisms and Applications: Annals of the New York Academy of Sciences</u>, 778:376-378 (1996)	<input type="checkbox"/>	<input type="checkbox"/>
	20.	Graham et al., <u>Methods in Molecular Biology</u>, 109-128 (The Human Press 1991)	<input type="checkbox"/>	<input type="checkbox"/>
	21.	Gregory, C. D. (Ed.), <u>Apoptosis and The Immune Response</u> (Wiley-Liss, Inc. 1995)	<input type="checkbox"/>	<input type="checkbox"/>
	22.	Guldotti et al., "High-Level Hepatitis B Virus Replication in Transgenic Mice," <u>J. Vir.</u>, 69(10):6158-6169 (1995)	<input type="checkbox"/>	<input type="checkbox"/>
	23.	Hancock et al., "Short Communication: Suppression of Insulinitis in Non-Obese Diabetic (NOD) Mice by Oral Insulin Administration Is Associated with Selective Expression of Interleukin-4 and -10, Transforming Growth Factor-beta, and Prostaglandin-E," <u>Am. J. Path.</u>, 147(5):1193-1199 (1995)	<input type="checkbox"/>	<input type="checkbox"/>
	24.	Hirahara et al., "CD4⁺ T Cells Anergized by High Dose Feeding Establish Oral Tolerance to Antibody Responses when Transferred in SCID and Nude Mice," <u>J. Immunol.</u>, 154:6238-6245 (1995)	<input type="checkbox"/>	<input type="checkbox"/>
	25.	Horwitz et al., "Synthesis and Assembly of Adenovirus 2: I. Polypeptide Synthesis, Assembly of Capsomeres, and Morphogenesis of the Virion," <u>Virology</u>, 39:682-694 (1969)	<input type="checkbox"/>	<input type="checkbox"/>
	26.	Horwitz, M.S., "Adenoviridae and Their Replication," <u>Virology</u>, Ch. 60, 1679-1721 (Raven Press 2nd ed. 1990)	<input type="checkbox"/>	<input type="checkbox"/>
	27.	Ilan et al., "Adoptive Transfer of Tolerance from Rats Centrally Tolerized to Adenoviral Antigens Allows Long-Term Adenovirus-Mediated Gene Therapy in Gunn Rats," <u>Hepatology: AASLD Abstracts</u>, 202A, 304 (1996)	<input type="checkbox"/>	<input type="checkbox"/>

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**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

(use as many sheets as necessary)

Application Number	09/356,294
Filing Date	7/16/1999
First Named Inventor	Rabbani, et al.
Art Unit	1644
Examiner Name	Ronald B. Schwadron

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OTHER DOCUMENTS - NON-PATENT LITERATURE DOCUMENTS

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	28.	Ilan et al., "Induction of Central Tolerance by Intrathymic Inoculation of Adenoviral Antigens into the Host Thymus Permits Long-term Gene Therapy in Gunn Rats," J. Clin. Invest., 98(11):2640-2647 (1996)	<input type="checkbox"/>	<input type="checkbox"/>
	29.	Ilan et al., "Transient Short Term FK-506 Treatment Permits Long Term Gene Expression Using Recombinant Adenoviruses Vectors," J. Hepatol.: Postgraduate Course and Abstracts of the 31st Annual Meeting of the European Association for the Study of the Liver, 23:73, WP3/019 (Suppl. 1 1996)	<input type="checkbox"/>	<input type="checkbox"/>
	30.	Jaffe et al., "Adenovirus-mediated in vivo gene transfer and expression in normal rat liver," Nature Genetics, 1:372-378 (1992)	<input type="checkbox"/>	<input type="checkbox"/>
	31.	Kerr et al., "Apoptosis: A Basic Biological Phenomenon with Wide-Ranging Implications in Tissue Kinetics," Br. J. Cancer, 26:239-257 (1972)	<input type="checkbox"/>	<input type="checkbox"/>
	32.	Kroemer, G. and Martinez, A., C. (Eds.), "Current Topics in Microbiology and Immunology," Apoptosis in Immunology (Springer-Verlag 1995)	<input type="checkbox"/>	<input type="checkbox"/>
	33.	Kuby, J., "Cancer and the Immune System," Immunology, 573-596 (W.H. Freeman and Company 3rd ed. 1997)	<input type="checkbox"/>	<input type="checkbox"/>
	34.	Lederer, J. A. and A. K. Abbas, "Cytokines in Specific Immune Responses," Samter's Immunologic Diseases, Vol. I, Ch. 10, 129-141 (Little, Brown and Company 5th ed. 1995)	<input type="checkbox"/>	<input type="checkbox"/>
	35.	Maeda et al., "Conjugates of Anticancer Agents and Polymers: Advantages of Macromolecular Therapeutics in Vivo," Bioconj. Chem., 3(5):351-362 (1992)	<input type="checkbox"/>	<input type="checkbox"/>
	36.	Maizel et al., "The Polypeptides of Adenovirus: II. Soluble Proteins, Cores, Top Components and the Structure of the Virion," Virology, 36:126-136 (1968)	<input type="checkbox"/>	<input type="checkbox"/>
	37.	Müller et al., "Relationship of antibodies against CD4⁺ T cells in HIV-infected patients to markers of activation and progression: autoantibodies are closely associated with CD4 cell depletion," Immunology, 79:248-254 (1993)	<input type="checkbox"/>	<input type="checkbox"/>
	38.	Peters et al., "Characterization and Tissue Specificity of a Monoclonal Antibody Against Human Uridine 5'-Diphosphate-Glucuronosyltransferase," Gastroenterology, 93:162-169 (1987)	<input type="checkbox"/>	<input type="checkbox"/>
	39.	Prevec et al., "Use of Human Adenovirus-based Vectors for Antigen Expression in Animals," J. Gen. Virol., 70:429-434 (1989)	<input type="checkbox"/>	<input type="checkbox"/>
	40.	Rich et al. (Eds.), Clinical Immunology: Principles and Practice, Vol. 2 (Mosby-2nd ed. 2001)	<input type="checkbox"/>	<input type="checkbox"/>



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Application Number	09/356,294
Filing Date	7/16/1999
First Named Inventor	Rabbani, et al.
Art. Unit	1644
Examiner Name	Ronald B. Schwadron

Sheet	4	of	5	Attorney Docket Number	59046.000033
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OTHER DOCUMENTS - NON-PATENT LITERATURE DOCUMENTS

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	41.	Roy-Crowdhury et al., "Bilirubin Mono- and Diglucuronide Formation by Human Liver <i>In Vitro</i> . Assay by High-Pressure Liquid Chromatography," <u>Hepatology</u> , 1(6):622-627 (1981)	<input type="checkbox"/>	<input type="checkbox"/>
	42.	Sachs et al., "Control of Programmed Cell Death in Normal and Leukemic Cells: New Implications for Therapy," <u>Blood</u> , 82(4):15-21 (1993)	<input type="checkbox"/>	<input type="checkbox"/>
	43.	Seglen, P. O., "Preparation of Isolated Rat Liver Cells," <u>Methods in Cell Biology</u> , Vol. 13, Ch. 4, 30-83 (1976)	<input type="checkbox"/>	<input type="checkbox"/>
	44.	Takahashi et al., "Acute hepatitis in rats expressing human hepatitis B virus transgenes," <u>Proc. Nat. Acad. Sci. USA</u> , 92:1470-1474 (1995)	<input type="checkbox"/>	<input type="checkbox"/>
	45.	Takahashi et al., "Long Term Correction of Bilirubin-UDP-glucuronosyltransferase Deficiency in Gunn Rats by Administration of a Recombinant Adenovirus during the Neonatal Period," <u>J. Biol. Chem.</u> 271(43):26536-26542 (1996)	<input type="checkbox"/>	<input type="checkbox"/>
	46.	Thompson, C.B., "Apoptosis in the Pathogenesis and Treatment of Disease," <u>Science</u> , 267:1456-1462 (1995)	<input type="checkbox"/>	<input type="checkbox"/>
	47.	Thomson, A.W. (Ed.), "Molecular Medical Science Series," <u>The Molecular Biology of Immunosuppression</u> (John Wiley & Sons, Inc. 1992)	<input type="checkbox"/>	<input type="checkbox"/>
	48.	Tilney et al. (Eds.), <u>Transplantation Biology: Cellular and Molecular Aspects</u> (Lippincott-Raven Publishers 1996)	<input type="checkbox"/>	<input type="checkbox"/>
	49.	Tomei, L.D. and Cope, F.O. (Eds.), "Apoptosis II: The Molecular Basis of Cell Death," <u>Current Communications: In Cell & Molecular Biology</u> , Vol. 3 (Cold Spring Harbor Laboratory Press 1991)	<input type="checkbox"/>	<input type="checkbox"/>
	50.	Tomei, L.D. and Cope, F.O. (Eds.), "Apoptosis II: The Molecular Basis of Apoptosis in Disease," <u>Current Communications: In Cell & Molecular Biology</u> , Vol. 8 (Cold Spring Harbor Laboratory Press 1994)	<input type="checkbox"/>	<input type="checkbox"/>
	51.	Towbin et al., "Electrophoretic transfer of proteins from polyacrylamide gels to nitrocellulose sheets: Procedure and some applications," <u>Proc. Natl. Acad. Sci. USA</u> , 76(9):4350-4354 (1979)	<input type="checkbox"/>	<input type="checkbox"/>
	52.	Trotman et al., "Azodipyrrroles of Unconjugated and Conjugated Bilirubin Using Diazotized Ethyl Anthranilate in Dimethyl Sulfoxide," <u>Analytical Biochemistry</u> , 121:175-180 (1982)	<input type="checkbox"/>	<input type="checkbox"/>
	53.	Vandenbark et al., "Definition of Encephalitogenic and Immunodominant Epitopes of Guinea Pig Myelin Basic Protein (Gp-BP) in Lewis Rats Tolerized Neonatally with Gp-BP or Gp-BP Peptides," <u>J. Immunol.</u> , 153:852-861 (1994)	<input type="checkbox"/>	<input type="checkbox"/>

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Substitute for form 1449A/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(use as many sheets as necessary)</i>		Application Number		09/356,294			
		Filing Date		7/16/1999			
		First Named Inventor		Rabbani, et al.			
		Art Unit		1644			
		Examiner Name		Ronald B. Schwab			
Sheet	5	of	5	Attorney Docket Number		59046.000028	
OTHER DOCUMENTS - NON-PATENT LITERATURE DOCUMENTS							
*Examiner Initials	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published				TRANSLATION	
	54.	Walter et al., "Successful expression of human factor IX following repeat administration of an adenoviral vector in mice," <u>Proc. Natl. Acad. Sci. USA</u> , 93:3056-3061 (1996)				<input type="checkbox"/>	<input type="checkbox"/>
	55.	Weiner, H.L. and Mayer, L.F. (Eds.), "Oral Tolerance: Mechanisms and Applications," <u>Annals of the New York Academy of Sciences</u> , Vol. 778 (1996)				<input type="checkbox"/>	<input type="checkbox"/>
	56.	Weiner, H.L., "Commentary: Oral tolerance," <u>Proc. Natl. Acad. Sci. USA</u> , 91:10762-10765 (1994)				<input type="checkbox"/>	<input type="checkbox"/>
	57.	Winkelstein, A., "Immunosuppressive Therapy," <u>Basic and Clinical Immunology</u> , Ch. 61, 766-779 (Appleton & Lange 7th ed. 1991)				<input type="checkbox"/>	<input type="checkbox"/>
	58.	Wyllie et al., "Cell Death: The Significance of Apoptosis," <u>International Review of Cytology</u> , 68:251-306 (1980)				<input type="checkbox"/>	<input type="checkbox"/>
	59.	Yang et al., "Cellular and Humoral Immune Responses to Viral Antigens Create Barriers to Lung-Directed Gene Therapy with Recombinant Adenoviruses," <u>J. Virol.</u> , 69(4):2004-2015 (1995)				<input type="checkbox"/>	<input type="checkbox"/>
	60.	Yang et al., "Inactivation of E2a in recombinant adenoviruses improves the prospect for gene therapy in cystic fibrosis," <u>Nature Genetics</u> , 7:362-369 (1994)				<input type="checkbox"/>	<input type="checkbox"/>
	61.	Zarling et al., "HIV-infected humans, but not chimpanzees, have circulating cytotoxic T lymphocytes that lyse uninfected CD4 ⁺ Cells," <u>J. Immunol.</u> , 144(8):2992-2998 (1990)				<input type="checkbox"/>	<input type="checkbox"/>
	62.	Zhao et al., "Skin graft tolerance across a discordant xenogeneic barrier," <u>Nature Med.</u> , 2(11):1211-1216 (1996)				<input type="checkbox"/>	<input type="checkbox"/>
	63.	Ziegler, J.L. and Stites, D.P., "Hypothesis: AIDS Is an Autoimmune Disease Directed at the Immune System and Triggered by a Lymphotropic Retrovirus," <u>Chn. Immunol. Immunopathol.</u> , 41:305-313 (1986)				<input type="checkbox"/>	<input type="checkbox"/>
EXAMINER SIGNATURE				DATE CONSIDERED		6/24/2000	
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